

Application No. 09/914,552  
Amendment dated August 25, 2003  
Reply to Office Action dated February 26, 2003

**REMARKS**

Reconsideration and continued examination of this application are respectfully requested. By this amendment claim 1 has been amended and claims 2-26 have been cancelled. New claims 27-48 have been added which, in part, are directed to reagent kits for measuring cholesterol in lipoproteins and methods of measuring cholesterol levels. The new claims are fully supported by the present application and no new matter has been added.

New independent claim 27, and claims that depend therefrom, are directed to a reagent kit. The claimed reagent kit comprises two reagents for measuring the cholesterol in high-density lipoproteins. The first reagent includes a compound that is able to increase ion strength of a reaction liquor and a non-ionic surfactant. The second reagent includes a first enzyme that is able to react with cholesterol in high-density lipoproteins, and a second enzyme selected from one of CDH (cholesterol dehydrogenase) and COD (cholesterol oxidase).

New independent claim 35, and claims that depend therefrom, are directed to a reagent kit. The claimed reagent kit measures cholesterol in low-density lipoproteins and comprises two selected reagents. The first reagent includes a compound that is able to increase ion strength of a reaction liquor, a first non-ionic surfactant, a first enzyme that reacts with the cholesterol in the high-density lipoprotein, and a second enzyme selected from CDH (cholesterol dehydrogenase) and COD (cholesterol oxidase). The second reagent includes a second non-ionic surfactant.

For the reasons stated below, the Applicants submit that amended claim 1 and new claims 27 and 35, and claims depending therefrom, are patentably distinct from the cited references.

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Favorable consideration and allowance of amended claim 1 and new claims 27-48 are respectfully requested.

At page 2 of the Office Action dated February 26, 2003, the Examiner requests that the specification be amended to include all related cases, including the Japanese patent application from which priority is claimed. The Examiner states that priority is granted to March 1, 1999. Applicants have amended the specification to note the claim of priority to Japanese Patent Application No. 11/53330, filed March 1, 1999.

At page 2 of the Office Action, the Examiner states that no foreign search report was found in the file and he requests a copy of any foreign search report. Applicants respectfully note that the Examiner indicated on forms PTO-1449, initialed and signed by the Examiner and dated January 21, 2003, that he reviewed and considered a copy of the IPER, dated December 21, 2001, and a copy of the Supplemental Partial European Search Report, dated June 27, 2002. Applicants are not aware of any additional foreign search reports.

At pages 2 and 3 of the Office Action, claims 1, 2, 4, 6, 15, 21, and 26 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,057,118 to Nakamura et al. (the '118 patent) and a publication entitled "Homogeneous Assay for Measuring Low-Density Lipoprotein Cholesterol In Serum With Triblock Copolymer and  $\alpha$ -Cyclodextrin Sulfate" (the Sugiuchi publication).

At pages 2 and 3 of the Office Action, claims 1, 2, 4, 6, 15, 21, and 26 were also rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,925,534 to Miki et al. (the '534 patent). The Examiner states that the claims of the '118 patent teach determining low-density

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lipoproteins (LDL) with a surfactant, a polyanion, with cholesterol esterase, and cholesterol oxidase. The Examiner states that the claims of the '534 patent teach determining LDL with a surfactant and a polyanion. The Examiner also states that the abstract of the Sugiuchi publication teaches determining LDL with POE-POP surfactant changes reactivity of lipoprotein fractions. The Examiner also states that cyclodextrin selectively reduces reactivity of cholesterol for determining LDL. Thus, the Examiner states that each of the features of the claims of the above-identified application are taught by each of the above-cited references for the same function as claimed. The Examiner also states that, with regard to claim 26, it is well known in the art to select pH ranges for desired enzymatic reactions expected to occur in a reproducible manner. For the following reasons, these rejections are respectfully traversed.

The '118 patent does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins or a method using the components in claim 1. The '118 patent also does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins that includes a set of two different types of selected reagents. The '118 patent also does not teach or describe that one of the reagents includes a compound that is able to increase ion strength of a reaction liquor. The '118 patent further does not teach or otherwise describe a reagent kit for measuring cholesterol in low density lipoproteins that includes a set of two different types of selected reagents. The '118 patent also does not teach or otherwise describe a first reagent that includes a compound that increases ion strength of a reaction liquor.

The '534 patent does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins or a method using the components in claim 1. The '534 patent also

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does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins that includes a set of two different types of selected reagents. The '534 patent also does not teach or otherwise describe that a first reagent includes a compound that is able to increase ion strength of a reaction liquor and that a second reagent includes a first enzyme and a second enzyme. The '534 patent does not teach or otherwise describe a reagent kit for measuring cholesterol in low-density lipoproteins that includes a set of two different types of selected reagents. The '534 patent also does not teach or otherwise describe a first reagent containing a compound that increases ion strength of a reaction liquor.

The Sugiuchi publication also does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins or the use of the components in the method of claim 1. The Sugiuchi publication also does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins that includes a set of two different types of selected reagents. The Sugiuchi publication also does not teach or otherwise describe that one of the reagents includes a compound that is able to increase ion strength of a reaction liquor and a non-ionic surfactant. The Sugiuchi publication does not teach or otherwise describe a reagent kit for measuring cholesterol in low-density lipoproteins that includes a set of two different types of selected reagents. The Sugiuchi publication also does not teach or otherwise describe a first reagent that includes a compound that increases ion strength of a reaction liquor, a first non-ionic surfactant, a first enzyme, and a second enzyme. Accordingly, the rejections should be withdrawn.

At page 3 of the Office Action, claims 3, 5, 7, 14, and 20 were rejected under 35 U.S.C. § 102(b) as being anticipated by a publication titled "Evaluation of Reactivity Using Direct Assay

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Methods for High Density Lipoprotein Cholesterol" (the Yamauchi publication) and U.S. Patent No. 4,892,815 to Kerscher et al. (the '815 patent). The Examiner states that the abstract of the Yamauchi publication teaches determining HDL with PEG modified enzymes or a polyanion and surfactant as compared to a precipitation method. The Examiner also states that column 2, lines 38-45 of the '815 patent teaches detergents and enzymes to determine HDL. The Examiner also suggests referring to the claims of the '815 patent. The Examiner states that each of the features of the claimed invention are taught by each of the above references for the same function as claimed.

For the following reasons, this rejection is respectfully traversed.

The '815 patent does not teach or otherwise describe a reagent kit comprising two groups of selected reagents, nor does it teach or otherwise describe the first reagent containing a compound that is able to increase ion strength of a reaction liquor or a method using the components of claim 1. The '815 patent does not teach or otherwise describe a reagent for measuring cholesterol in low-density lipoproteins. The '815 patent also does not teach or otherwise describe a reagent kit that measures cholesterol in low-density lipoproteins that includes a set of two different types of selected reagents. The '815 patent also does not teach or otherwise describe a reagent that includes a compound that is able to increase ion strength of a reaction liquor.

The Yamauchi publication also does not teach or otherwise describe a reagent kit comprising two groups of selected reagents, nor does it teach or otherwise describe the use of a first reagent that includes a compound that is able to increase ion strength of a reaction liquor and a non-ionic surfactant. The Yamauchi publication does not teach or otherwise describe a reagent for measuring cholesterol in low-density lipoproteins. The Yamauchi publication also does not teach

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or otherwise describe a reagent kit for measuring cholesterol in low-density lipoproteins that includes a set of two different types of selected reagents. The Yamauchi publication also does not teach or otherwise describe a first reagent that includes a compound that is able to increase ion strength of a reaction liquor and a first non-ionic surfactant. The Yamauchi publication also does not teach or otherwise describe a second reagent that contains a second non-ionic surfactant. For these reasons, the rejection should be withdrawn.

At page 4 of the Office Action, claims 16-19 and 22-25 were rejected under 35 U.S.C. § 102(a) as being anticipated by the '118 patent. The Examiner states that the claims of the '118 patent teach determining LDL with a surfactant, a polyanion, with cholesterol esterase, and cholesterol oxidase. The Examiner states that in column 3, various methods of determining VLDL are shown with polyanion and surfactants. The Examiner states that each of the claims are taught by the '118 patent for the same function as claimed. For the following reasons, this rejection is respectfully traversed.

The '118 patent does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins or a method of using these components. The '118 patent also does not teach or otherwise describe a reagent kit for measuring cholesterol in high-density lipoproteins that includes a set of two different types of selected reagents. The '118 patent also does not teach or describe that one of the reagents includes a compound that is able to increase ion strength of a reaction liquor. The '118 patent does not teach or otherwise describe a reagent kit for measuring cholesterol in low density lipoproteins that includes a set of two different types of selected reagents.

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The '118 patent also does not teach or otherwise describe a first reagent that includes a compound that increases ion strength of a reaction liquor. Accordingly, the rejection should be withdrawn.

At page 4 of the Office Action, claims 2-7 and 15-26 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Examiner states that dependent claims must begin with a definite article. The Examiner also states that, in claim 18 and all other occurrences, "the [sic] have the cholesterol component remained" is not understood in context. For the following reasons, this rejection is respectfully traversed.

The Applicants have corrected all dependent claims to ensure that they begin with a definite article. Applicants have cancelled claims 2-7 and 15-26. Applicants submit that the present claims overcome the present rejections. Applicants respectfully request reconsideration and continued examination of the application.

At page 5, the Examiner states that the title of the invention is not aptly descriptive. The Examiner states that a title that is clearly indicative of the invention to which the claims are directed is required.

In response, the Applicants have amended the title of the invention herein to clearly reflect the claimed invention.

In view of the remarks above, withdrawal of the rejections and objections and continued examination of the application are respectfully requested.

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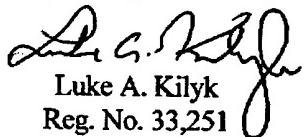
**CONCLUSION**

In view of the foregoing remarks, Applicants respectfully request favorable reconsideration of the present application and a timely allowance of the pending claims.

Should the Examiner deem that any further action by Applicants or Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

If there are any other fees due in connection with the filing of this response, please charge the fees to deposit Account No. 50-0925. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such extension is requested and should also be charged to said Deposit Account.

Respectfully submitted,

  
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